REMARKS/ARGUMENTS

Reconsideration is respectfully requested in view of the remarks presented herein.

Status of the Claims

Claims 1-10, 16, 17, 19 and 20 are pending in the application. Claims 11-15, 18, and 21-28 have been withdrawn from consideration by the Examiner has drawn to non-elected subject matter.

Response to the Rejection under 35 U.S.C. §103(a) in view of Yang et al.

Claims 1-10, 16, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over U.S. Patent No. 7,425,292 to Yang et al. ("Yang et al."). In particular, the Examiner has alleged that Yang et al. "meets the edible film as claimed based upon the same features and elements." (Office Action, page 5). Applicants respectfully traverse the rejection under 35 U.S.C. §103(a) for the reasons set forth below.

Applicants respectfully submit that Yang et al. is disqualified under 35 U.S.C. §103(c) as prior art in a rejection under 35 U.S.C. §103(a). MPEP §706.02(l)(2) states that "[i]n order to be disqualified as prior art under 35 U.S.C. 103(c), the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made . . . ." MPEP §706.02(l)(2).

As stated in the "Statement Regarding Common Ownership" being filed concurrently herewith, to the best of the undersigned's knowledge, the present application (*i.e.*, U.S. Application No. 10/521,823) and U.S. Application No. 10/074,272 (which issued as U.S. Patent No. 7,425,292 to Yang et al.) were commonly owned, or under an obligation of assignment to the same entity, at the time that the claimed invention of the present application was made. In this regard, submitted herewith are the following:

- copy of an Assignment of Invention and accompanying Notice of Recordation for U.S. Application No. 10/074,272 (which issued as U.S. Patent No. 7,425,292 to Yang et al.) from inventors Robert Yang (executed April 5, 2002), Richard Fuisz (executed April 4, 2002), G. Myers (executed April 5, 2002), and Joseph Fuisz (executed April 4, 2002) to Kosmos Pharma (Recorded at Reel/Frame 013002/0285); and

- copy of an Assignment of Invention and accompanying Notice of Recordation for priority U.S. Application No. 60/397,703 from inventors Robert Yang (executed December 24, 2002), Richard Fuisz (executed December 27, 2002), G. Myers (executed January 7, 2003), and Joseph Fuisz (executed December 27, 2002) to Kosmos Pharma (Recorded at Reel/Frame 013688/0136).

Kosmos Pharma Limited subsequently conveyed U.S. Application No. 10/074,272 (which issued as U.S. Patent No. 7,425,292 to Yang et al.) to Monosol Rx, LLC. In this regard, the following documents are attached:

- Assignment Agreement between Kosmos Pharma Limited (Selling Party) and Monosol Rx, LLC (Buying Party) (executed January 23, 2004) for U.S. Application No. 10/074,272 (which issued as U.S. Patent No. 7,425,292 to Yang et al.) (Recorded at Reel/Frame 014315/0613); and

- Notice of July 10, 2007 for U.S. Application No. 10/074,272 (which issued as U.S. Patent No. 7,425,292 to Yang et al.) and accompanying Notice of Recordation (Recorded at Reel/Frame 019537/0247).

Moreover, Kosmos Pharma subsequently assigned priority U.S. Application No. 60/397,703 and the present application (*i.e.*, U.S. Application No. 10/521,823) to MonoSolRx, LLC. In this regard, the following documents are attached:

- Assignment of Invention from Kosmos Pharma to MonoSolRx, LLC (executed September 1, 2005) for priority U.S. Application No. 60/397,703 and the present application (*i.e.*, U.S. Application No. 10/521,823) (Recorded at Reel/Frame 016515/0096); and

- Corrective Assignment (Recorded at Reel/Frame 019698/0054) for the assignment recorded at Reel/Frame 016515/0096 to correct the name of the assignee to MonoSol Rx, LLC.

In view of the foregoing, it is respectfully submitted that the Yang et al. reference is disqualified under 35 U.S.C. §103(c) as prior art in a rejection under 35 U.S.C. §103(a) pursuant to MPEP §706.02(l)(2). Accordingly, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) with regard to claims 1-10, 16, 17, 19 and 20 in view of Yang et al.

Response to the Rejection under 35 U.S.C. §103(a) in view of Cremer et al.

Claims 1-7, 16, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over U.S. Patent No. 6,655,112 to Cremer et al. ("Cremer et al."). In particular, the Examiner has alleged that "Cremer meets the edible film as claimed based upon the same features and elements." (Office Action, page 6). Applicants respectfully traverse the rejection for the reasons set forth below.

As required by *KSR International v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385 (2007), a rationale must be provided to support an obviousness rejection. (*See* MPEP §2141.III.) In particular, MPEP §2141.III sets forth seven permissible rationales under *KSR*, with five of those rationales requiring predictability and with the fifth rationale requiring a reasonable expectation of success. Indeed, as stated in MPEP § 2143.02.II, "at least some degree of *predictability* is required." *See* MPEP § 2143.02.II. (Emphasis added). However, no rationale under *KSR* has

been provided by the Examiner, let alone a showing of predictability of results. As such, the Examiner has failed to establish a *prima facie* case of obviousness.

Moreover, none of the cited rationales would support a *prima facie* case of obviousness in view of Cremer et al. Contrary to the contention of the Examiner at page 6 of the Office Action, Cremer et al. does not meet "the edible film as claimed based upon the same features and elements." Significantly, no reasoning has been provided by the Examiner as to why one of ordinary skill in the art would view the particular passages relied on by the Examiner with respect to Cremer et al. as "meeting" the features and elements of claims 1-7, 16-17, 19, and 20. Moreover, it is respectfully submitted that the very passages relied on by the Examiner actually evidence that Cremer et al. teaches away from a film which includes multiple dosage units.

As acknowledged by the Examiner, Cremer et al. discloses individually sealed dosage units. (*See* abstract of Cremer et al.). As further acknowledged by the Examiner, Cremer et al. discloses perforations between the compartments which enable the separation of the individual compartments (*see* abstract, and col. 3, line 55-col. 4, line 47, of Cremer et al.). Accordingly, the perforations in Cremer et al. are within a packaging material and not within the film itself. Specifically, the perforations are included between the compartments in Cremer et al. to allow an individual compartment containing a single dosage unit to be separated from the primary packing unit prior to the opening of the compartment itself, thereby allowing the extraction of a single dosage unit (*see* col. 4, lines 26-28, of Cremer et al.).

Indeed, viewing Cremer et al. in its entirety as an analysis under 35 U.S.C. §103(a) requires, Cremer et al. is directed to a "primary packaging unit for solid administration forms in individual doses" which "enable the deliberate and controllable removal of a single dosage unit at the desired time of intake" (*see* column 1, lines 48-53, of Cremer et al.). To that end, as noted above, the perforations in Cremer et al. are between the compartments of the packaging material

of Cremer et al. and not within the film itself (*see* column 3, lines 65-67, and column 4, lines 22-23, and 26-28, of Cremer et al.). As such, Cremer et al. fails to disclose or suggest a film which includes dosage units releasably joined by one or more weakened sections which permit the dosage units to be detached from the film, as required by all of claims 1-7, 16, 17, 19, and 20.

Indeed, having a film which includes multiple dosage units would be in direct contradiction to Cremer et al.'s purpose of providing single dosage units which are sealed into compartments and which are completely enclosed by sealed seams or sealed areas. Moreover, any modification of Cremer et al.'s film to anything other than single dosage units would render the film of Cremer unsuitable for its intended purpose of being separately packaged.

In view of the foregoing, Applicants respectfully submit that claims 1-7, 16, 17, 19 and 20 are not obvious in view of Cremer et al. Accordingly, Applicants respectfully withdrawal of the rejection under 35 U.S.C. §103(a) with regard to claims 1-7, 16, 17, 19, and 20 in view of Cremer et al.

Response to the Rejection under 35 U.S.C. §103(a) in view of Chen et al.

Claims 1-10, 16, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over WO 00/42992 to Chen et al. ("Chen et al."). In particular, the Examiner has alleged that Chen et al. "meets the edible film as claimed based upon the same features and elements." (Office Action, page 6). Applicants respectfully traverse the rejection for the reasons set forth below.

As required by *KSR International v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385 (2007), a rationale must be provided to support an obviousness rejection. (*See* MPEP §2141.III.) In particular, MPEP §2141.III sets forth seven permissible rationales under *KSR*, with five of those rationales requiring predictability and with the fifth rationale requiring a reasonable expectation

of success. Indeed, as stated in MPEP § 2143.02.II, "at least some degree of *predictability* is required." *See* MPEP § 2143.02.II. (Emphasis added). However, no rationale under *KSR* has been provided by the Examiner, let alone a showing of predictability of results. As such, the Examiner has failed to establish a *prima facie* case of obviousness.

None of the cited rationales, however, would support a *prima facie* case of obviousness in view of Chen et al. Contrary to the contention of the Examiner at page 6 of the Office Action, Chen et al. does not meet "the edible film as claimed based upon the same features and elements." Significantly, no reasoning has been provided by the Examiner as to why one of ordinary skill in the art would view the particular passages relied on by the Examiner with respect to Chen et al. as "meeting" the features and elements of claims 1-10, 16, 17, 19, and 20.

Although Chen et al. terms "strip 19" at Figure 3 as a "perforated film strip 19," one of ordinary skill in the art would appreciate that the "perforated film strip 19" of Chen is a strip of film which has already been completely cut into single dose film units. As such, the "perforated film strip 19" of Chen et al. is not a film including dosage units which are releasably joined by one or more weakened sections which permit the dosage units to be detached from the film, as required by claims 1-10, 16, 17, 19 and 20.

Moreover, unlike the present application, Chen et al. is not at all directed to providing film which has weakened sections which permit for ease of administration of a single dosage unit. Rather, viewing Chen et al. in its entirety as analysis under 35 U.S.C. §103(a) requires, Chen et al. is directed to overcoming problems attendant delivery of active agents in solid form via the mouth (particularly, the potential for choking). (*See* page 6, lines 19-20, of Chen et al.). In this regard, Chen et al. is directed to providing dosage units which are not mobile in the mouth. (*See* page 6, lines 21-22, of Chen et al.). As such, Chen et al. has absolutely nothing to

do with providing films which have weakened sections to permit separation of dosage units from the film.

In view of the foregoing, Applicants respectfully submit that claims 1-10, 16, 17, 19, and 20 are not obvious in view of Chen et al. Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

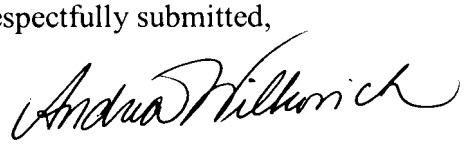
Concluding Remarks

This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned at the telephone number given below.

No fees are deemed due with this submission. However, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this submission or any future submission pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



Andrea M. Wilkovich
Registration No.: 53,773

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700